Making the Case for Ma$$ $pectrometry

How to convince administration THEY want to buy YOU a mass spectrometer

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INTRODUCTION

The acquisition of a mass spectrometer to enhance a hospital's clinical laboratory capabilities is a scientific and business decision. The additional capability, both initially and in the future, is a scientific decision. Justifying spending the money necessary to acquire and implement mass spectrometry-based assays is a business decision. To convince those who review budgets to allocate the funds necessary to establish mass spectrometry-based capabilities requires scientists to learn some "business-speak." Like clinical analysis, business-speak has well-defined concepts and terms scientists must learn to communicate effectively.

DEVELOPING A SUCCESSFUL BUSINESS CASE

The primary concept to be conveyed is that of the "business case," a financial justification for spending large sums of money to acquire added capability and other eventual advantages. Components of the business case include profit, return on investment (ROI), and payback period. To establish a case, a scientist must be able to identify and accurately quantify costs associated with the proposed instrument system, facility improvements, staffing, and workflow.

While scientists know the scientific terminology and can justify advantages of proposed equipment, they often do not know the particulars of business-speak. Without having a science-to-business translator to help translate those needs and advantages, chances of finding internal funding for new, novel instrumentation like a mass spectrometer approaches zero. Scientists must temporarily abandon their thought processes learned in graduate school and adapt to using language taught in business school. Fortunately, business-speak is not a difficult language to learn and does not require advanced mathematics.

ASSESSING COSTS ASSOCIATED WITH MASS SPECTROMETRY

When developing a convincing business case for the purchase of new mass spectrometry, one must first create a detailed document that outlines costs associated with the desired acquisition—initial and ongoing—and potential revenue that can be generated using the new capability. The difference between the revenue generated by the new instrument and the associated costs will be the profit, and the amount of profit is a major determinant of whether or not the investment in new technology is worth making.

Defining the business case for the purchase of an expensive piece of capital equipment must be extended over several years. Not all money is created equal. Capital equipment (nonexpendable, high-cost tangible property with a useful life of more than one year) needs to be perceived differently than operational equipment for tax purposes. Each organization has a well-defined purchase price limit and considerations regarding capital equipment depreciation are also considered. The initial investment and operating expenses will occur during the first year of the purchase. With some luck, some revenue, or gross profit, may occur. Following the first year (years 2 through 5), gross profit must be greater than operating expenses to generate a net profit (**FIGURE 1**).

Once profit has been projected, the payback period and ROI can be calculated (**FIGURE 2**). The payback period can be determined by calculating how long it will take for the initial investment to be recouped. ROI is a different approach to evaluating investments. The calculation generates a fractional, or a percentage, relating the amount of profit to the size of the investment. ROI is a useful calculation for comparing potential investments.

The most difficult task for a scientist is to estimate the costs associated with introducing the new technology. In addition to defining the instrument's purchase price, one must also consider costs associated with facilities, staffing, and workflow (**FIGURE 3**). Costs impacting facilities need to be considered *prior* to installation of new equipment. If not, a delay in

FIGURE 1: Considerations when building out a business case.

	Year 1	Year 2	Year 3	Year 4	Year 5
Investment	-$				
Gross Profit	+$	+$	+$	+$	+$
Operating Expenses	-$	-$	-$	-$	-$
Net Profit	$	$	$	$	$

ROI = ?
PB = ?

FIGURE 2: Important calculations when determining revenue after investment.

$$\text{ROI} = \frac{(\text{Return/Profit} - \text{Investment})}{(\text{Investment})}$$

$$\text{Profit} = (\text{Revenue} - \text{Operational Expenses})$$

$$\text{Payback Period} = \frac{\text{Investment}}{\text{Annual Revenue}}$$

FIGURE 3: Estimating costs for a new mass spectrometry system.

If someone abracadabra'd a mass spec into your lab right now…what else would you need?

Facilities	Staffing	Workflow
SPACE	*TIME*	*CONSUMABLES*
VENTING	*PEOPLE*	*PERIPHERAL EQUIPMENT*
DATA DROPS		
ELECTRIC		

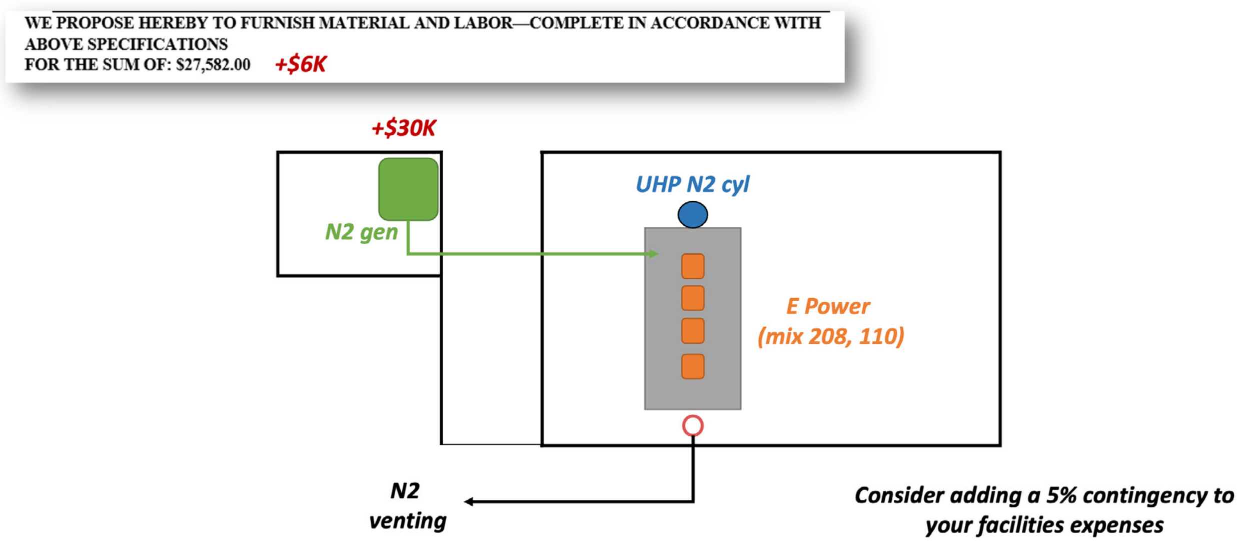
installation will likely occur and revenue is likely to suffer. Staffing should be a fixed cost, irrespective of the number of samples analyzed. The cost of consumables, on the other hand, excluding the instrument service contract, will vary almost directly with the number of samples analyzed.

Facilities

Facilities costs are the most difficult to estimate because they are the most complex and require the participation of facilities engineering staff. Space, venting, data drops, and electric are just a few examples of the various things one must consider when purchasing a new mass spectrometry system.

The simplest thing to estimate is the amount of bench space required for the instrument and supporting equipment. Power requirements are also relatively easy to obtain, as long as all instrumentation and equipment necessary for operation have been identified.

FIGURE 4: Retrofitting spaces for mass spectrometry.



All mass spectrometers require support gases. LC-MS instruments require a large volume of high purity grade nitrogen for the atmospheric pressure ionization source. The "house" nitrogen system must be of high enough purity and large enough capacity to fulfill demands. The cost of a nitrogen generator must be included when one looks at purchase price, bench space, and power demands (**FIGURE 4**).

Staffing

One of the more difficult variables to estimate when building out the case for a new mass spectrometry system is the cost of staffing. This is especially difficult if there is limited in-house expertise. Organizations may consider promoting from within, hiring new personnel, or seeking assistance from a consultant (**FIGURE 5**).

One option is to "promote" established scientists from within the organization. The advantage of this approach is that the person(s) being promoted are already familiar with the organization, its mission, culture, and structure. However, training on the use of the main instrument, supporting equipment, and maintenance are still necessary. The training process is both time-consuming and expensive. One may need to consider the required costs for hands-on training courses and associated travel, although travel and training are sometimes desired perks for a valued employee.

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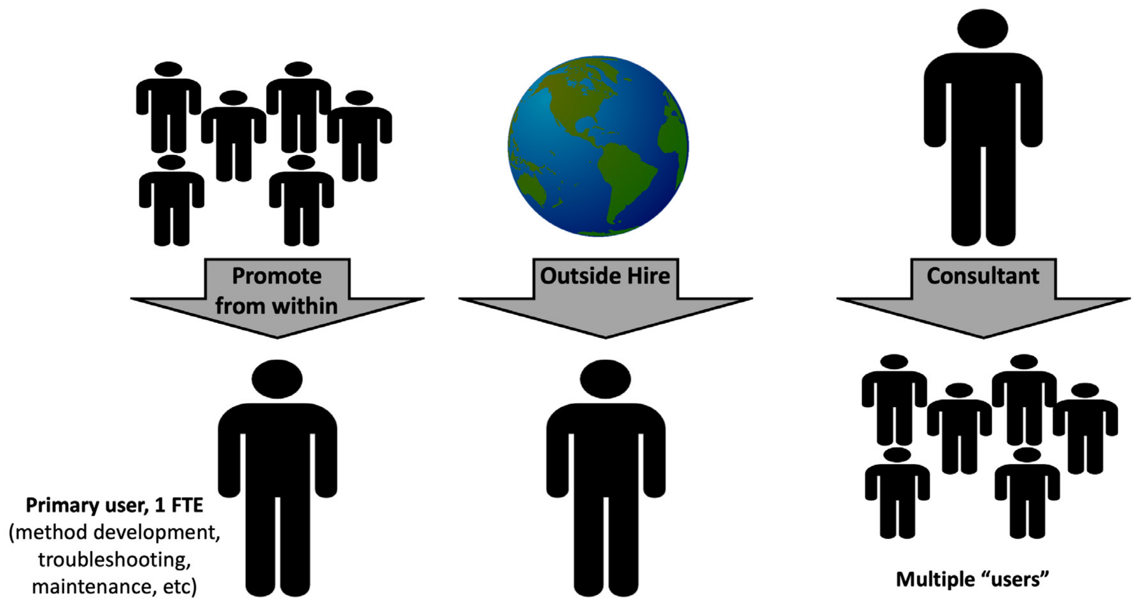
FIGURE 5: Staffing approaches.



Hiring experienced analysts from outside the company is another option. This approach should reduce training costs significantly, but will take time and effort. Identifying and hiring qualified scientists from outside is also likely to result in higher personnel costs. Outside hires need time to adapt to their new environment, and there is always the risk of hiring someone who is deemed unqualified.

A third approach is to hire an outside consultant to develop, implement, and validate the desired analyses and train a larger number of in-house scientists to perform the analysis at the end of the consultant's contract. The validated method will be ready to generate revenue when the consultant leaves, and the organization will have a supply of trained analysts to generate revenue on an ongoing basis. The disadvantage to this approach is the cost of the consultant.

Workflow

Estimating workflow costs is as complex as estimating facilities costs because of the number of fixed and variable costs associated with the analysis of samples. One significant fixed cost is the cost-of-service contracts for all critical instrumentation; a reasonable estimate for the cost of a standard service contract is 10% of the purchase price of the instrument.

Costs associated with chromatographic columns can be expensive, and the use of guard columns can increase the life of the much more expensive analytical column. The use of more extensive sample preparation, producing a "cleaner" sample, can also prolong the life of the analytical column and, perhaps, shorten the analytical cycle time. However, additional sample prep consumables will increase cost and sample preparation time. In terms of a 96-well plate sample preparation, an increase in sample preparation time is much less important than a reduction in sample analysis time. The cost of mobile phase, especially acetonitrile, is a cost that must be accounted for. Although only small volumes of solvent are required for each sample, the number of samples, including calibration and quality control samples, will consume a significant volume of solvent if the analyses are to be profitable.

FIGURE 6: Variables to consider when assessing workflow costs.

	$/unit	Units/Yr	$/Yr	$/sample
Chromatography				
Column (~1000 inj)				
Mobile Phase				
Calibrators				
Quality Control				
Internal Standards				
Sample Prep				
SPE?				
Misc Consumables				
Enzyme (tox)?				
96-well plates				
Pipette tips				
Service Contracts				

Calibration, quality control, and isotopically labeled internal standard costs are other variable costs that must be accounted for (**FIGURE 6**). Calibration samples can be produced in-house and are relatively inexpensive, although matrix matching can present some challenges. Accuracy and precision using relevant measurement tools is important. Vendor-prepared materials from certified providers are more expensive but are a more reliable source. Producing in-house quality control samples is less difficult since absolute accuracy is not a requirement.

Mass spectrometry is an extremely reliable quantitative analysis technique because of the ability to use isotopically labeled internal standards instead of homologs. The most common isotopes employed for labeling internal standards are ^{13}C and ^{2}H, with ^{2}H being significantly less expensive. Deuterium labels are less expensive because they are easier to incorporate into the molecule. But easier in also means easier out, as hydrogens can scramble position during ionization and mass analysis. Incorporating deuterium into the molecule also alters the chromatographic retention time; this can introduce a challenge in a complex chromatogram with closely eluting peaks. The most important consideration for isotopically labeled internal standards is the determination of the number and placement of labels in the molecule. When developing a business case, one must consider how long the synthesis of the internal standard will take. Time is likely far more important than cost.

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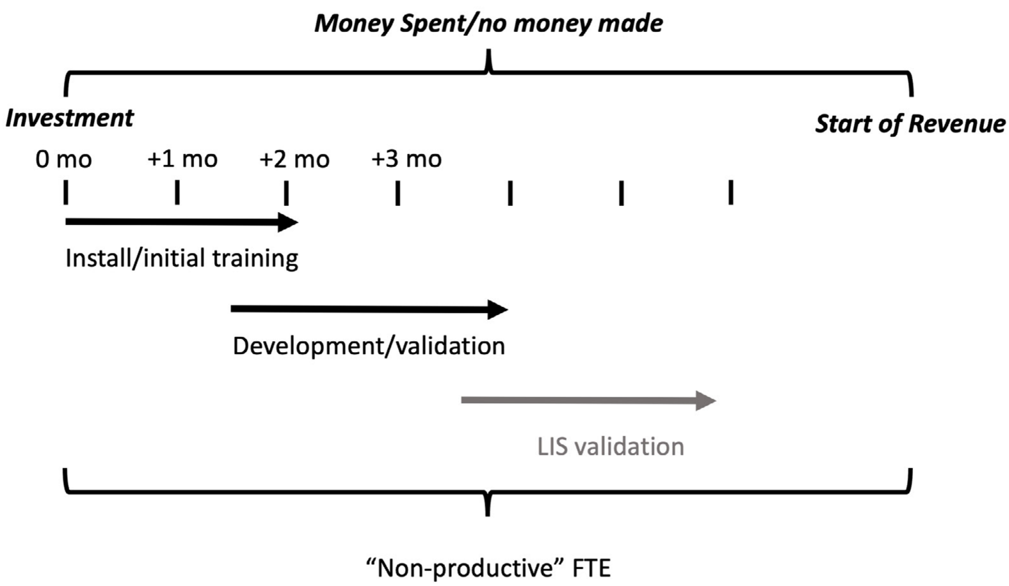
FIGURE 7: Mass Spec implementation timeline example.



PROJECTING REVENUE

The aspect of a business case that is similar to gazing into a crystal ball is the projection of when the new technology will begin producing revenue. The profit clock is ticking from the moment the check for the instrument purchase is issued or when the site preparation has begun. It is imperative to iron out all aspects when estimating profit—site preparation; instrument installation; operator training; method development; acquisition of calibration, quality control, and isotopically labeled internal standards; method validation; and the analysis of revenue-generating samples.

If the introduction of this new technology is to bring in-house the capability that is being provided by an outside laboratory, the any revenue generated will ramp up quickly. If this capability is to create new products, however, there may be a lag in time until sample analysis approaches full capacity. An example of a mass spectrometry system timeline (**FIGURE 7**) demonstrates the typical amount of time for which a company may begin to establish revenue following the initial investment of a new system.

CONCLUSION

Purchasing a new mass spectrometry system can greatly enhance a laboratory's capability to meet demands and generate additional revenue. However, mass spectrometers, support equipment, and supplies are expensive, and skilled operators are required. To justify the addition of mass spectrometry to the lab, a business case must be made. The business case provides details related to the costs, potential revenue, and timeline necessary when investing in a new system and can help determine if the acquisition makes business sense and is a good investment.